No. 23-35052

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JEREMY OLSEN,

Plaintiff-Appellant,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,

Defendant-Appellee.

On Appeal from the United States District Court for the Eastern District of Washington

SUPPLEMENTAL EXCERPTS OF RECORD
VOLUME 1 OF 1

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INDEX

Page

CMS Rulings | **Department of Health and Human Services**

Centers for Medicare & Medicaid Services

Ruling No.: CMS-1738-R | Date: May 13, 2022

CMS Rulings are decisions of the Administrator that serve as precedent final opinions or orders or statements of policy or interpretation. They are published under the authority of the Administrator of the Centers for Medicare & Medicaid Services (CMS).

CMS Rulings are binding on all CMS components, on all Department of Health and Human Services (HHS) components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration (SSA) to the extent that components of the SSA adjudicate matters under the jurisdiction of CMS.

This Ruling provides notice of the CMS Administrator's determination to rescind a January 17, 2017 CMS Ruling (CMS-1682-R) (hereinafter referred to as the January 2017 Ruling), and instead apply the terms of the December 28, 2021 final rule (86 FR 73860 through 73902) (hereinafter referred to as the December 2021 final rule), and this Ruling, to Medicare Part B and Part C claims for payment for continuous glucose monitors (CGMs). February 28, 2022 is the effective date of the December 2021 final rule, and claims for payment for a CGM monitor or receiver and/or its necessary supplies and accessories furnished to a Medicare beneficiary on or after February 28, 2022 shall be classified, covered, and paid in accordance with the December 2021 final rule. As for CGMs furnished before February 28, 2022, this Ruling provides that the substantive CGM classification, coverage, and payment policies

established by the December 2021 final rule shall be applied to claims for a CGM monitor or receiver and/or its necessary supplies and accessories where either: (1) a valid CGM claim or valid CGM appeal was pending as of February 28, 2022; or (2) the right to submit a valid CGM claim or file a valid CGM appeal had not expired as of February 28, 2022.

M**EDICARE PROGRAM**

SUPPLEMENTARY MEDICAL INSURANCE (PART B) AND MEDICARE ADVANTAGE PROGRAM (PART C)

CLASSIFICATION, COVERAGE, AND PAYMENT FOR CONTINUOUS GLUCOSE MONITORS AS DURABLE MEDICAL EQUIPMENT

CITATIONS: Sections 1861(n) and 1852 of the Social Security Act (42 U.S.C. 1395x(n) and 42 U.S.C. 1395w-22) and 42 CFR 414.202 and 42 CFR 422.101.

BACKGROUND

1. Medicare Classification, Coverage, and Payment for Continuous Glucose Monitors as Durable Medical Equipment

Medicare Part B provides for coverage and payment of certain durable medical equipment (DME). DME is a benefit category under Medicare Part B, defined at section 1861(n) of the Act. The term durable medical equipment is further defined and addressed in regulation and program instructions (see 42 CFR 414.202 and section 110.1 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02), respectively).

Under § 414.202, durable medical equipment means equipment which

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;

- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be DME under Medicare Part B. Also, Medicare coverage generally requires that the item or service was reasonable and necessary for the diagnosis or treatment of illness or injury. Section 1862(a)(1)(A) of the Act (42 U.S.C. 1395y(a)(1)(A)); 42 CFR 411.15(k)(1).

Under Medicare Part C, Medicare Advantage organizations (MAOs) must provide Medicare Advantage (MA) plan enrollees, either directly or through contracts with providers, with certain basic benefits consisting of all covered benefits under Medicare Parts A and B (except for hospice care or coverage for organ acquisitions for kidney transplants), and generally offer at least one plan option that covers benefits under Part D. Section 1852(a)(1) of the Act (42 U.S.C. 1395w-22(a)(1)); 42 CFR 422.100(a) and (c)(1) and 422.101. DME covered under Part B is among the basic benefits that MAOs must provide under Part C (42 CFR 422.100(l)).

CGMs are systems that use disposable glucose sensors to monitor a patient's interstitial fluid glucose levels on a continuous basis. The interstitial fluid glucose level is a reflection of the patient's blood glucose level, which is then displayed by the CGM monitor or receiver. A "therapeutic" or "non-adjunctive" CGM provides such monitoring without requiring the use of another device such as a blood glucose monitor for verifying the patient's blood glucose level. A "non-therapeutic" or "adjunctive" CGM requires an additional blood glucose determination using a device like a blood glucose monitor to verify the accuracy of the CGM's measurement. Additionally, certain insulin pumps can also function as a CGM monitor or receiver.

The January 2017 Ruling was issued on January 12, 2017, and is entitled Classification of Therapeutic Continuous Glucose Monitors as "Durable Medical Equipment" Under Part B. The January 2017 Ruling classified therapeutic or non-adjunctive CGMs as DME. If a certain therapeutic or non-adjunctive CGM met the criteria for DME, then it would be covered if the specific CGM was reasonable and necessary for treatment of illness or injury for the Medicare beneficiary. The January 2017 Ruling also addressed the calculation of fee schedule payment amounts for therapeutic or non-adjunctive CGMs under section 1834(a) of the Act (42 U.S.C. 1395m(a)) and 42 CFR part 414, subpart D.

However, the January 2017 Ruling rejected classification of non-therapeutic or adjunctive CGMs as DME because such CGMs require an additional device like a blood glucose monitor to verify blood glucose levels. Also, the January 2017 Ruling did not specifically address DME classification of insulin pumps that also function as a CGM monitor or receiver.

Final agency decisions denying coverage of non-therapeutic or adjunctive CGMs based on the January 2017 CMS Ruling were challenged in several lawsuits. In each case to reach the merits, the court concluded that Medicare should cover non-therapeutic or adjunctive CGMs. (*See Olsen v. Cochran*, No. 2:20-cv-00374-SMJ, 2021 WL 711469 at *3-4 (E.D. Wash. February 23, 2021) (summarizing cases).)

Informed in part by this line of judicial precedent, CMS engaged in notice and comment rulemaking regarding classification, coverage, and payment for CGMs. The result was the previously referenced December 2021 final rule, which established the same classification and coverage policies for all three types of CGMs: therapeutic or non-adjunctive CGMs; non-therapeutic or adjunctive CGMs; and insulin pumps that also function as a CGM monitor or receiver. The December 2021 final rule provides that disposable supplies and accessories

essential for the use of CGMs can be covered under the DME benefit regardless of which of these three types of CGMs is used. Because smartphones, tablets, or other similar devices that can also function as a CGM monitor or receiver are also useful to an individual in the absence of an illness or injury, such smartphones, tablets, or other similar devices are not classified as DME. However, if a Medicare beneficiary uses a smartphone or other similar non-DME device to display their glucose readings in conjunction with one of the three types of CGMs which they use as their primary display device, Medicare will cover disposable supplies and accessories pursuant to the December 2021 final rule because the beneficiary is using their covered CGM device as their primary display device for their glucose readings. In the case of an insulin pump that doubles as a CGM receiver, it must be determined that both the insulin pump and CGM are reasonable and necessary for the treatment of illness or injury for the beneficiary in order for the insulin pump/CGM receiver combination and related supplies and accessories for this equipment to be covered. The December 2021 final rule also addressed payment policies for the different types of CGMs.

As noted previously, February 28, 2022 is the effective date of the December 2021 final rule. Thus, claims for a CGM monitor or receiver and/or its necessary supplies and accessories furnished to a Medicare beneficiary on or after February 28, 2022 must be classified, covered, and paid as DME in accordance with the December 2021 final rule.

CMS addressed CGMs furnished before February 28, 2022 in its Technical Direction Letter-220257 (February 25, 2022) ("the 2022 TDL"). The 2022 TDL provides that, for CGMs furnished before February 28, 2022, the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule must also be applied to claims for payment for a CGM monitor or receiver and/or its necessary supplies and accessories where either (1) a

valid CGM claim or valid CGM appeal was pending as of February 28, 2022; or (2) the right to submit a valid CGM claim or file a valid CGM appeal had not expired as of February 28, 2022. As set forth later in this section, this Ruling reiterates and effectively replaces the essential terms of the 2022 TDL.

The December 2021 final rule replaced the 2017 CMS Ruling, CMS-1682-R, for CGMs furnished on or after February 28, 2022. Taken together, the December 2021 final rule and this Ruling prohibit further application of the January 2017 Ruling on CGMs, as CMS has determined that, in addition to therapeutic or non-adjunctive CGMs, non-therapeutic or adjunctive CGMs and insulin pumps that also function as a CGM monitor or receiver can also meet the definition of DME at 42 CFR 414.202. As set forth later in this section, this Ruling rescinds the January 2017 Ruling and applies the CGM classification, coverage, and payment provisions of the December 2021 final rule to valid CGM claims and valid CGM appeals for CGM monitors or receivers and/or necessary supplies and accessories furnished before February 28, 2022 under certain conditions. By rescinding the January 2017 Ruling, this Ruling will avoid the expenditure of administrative resources on further application of the January 2017 Ruling on CGMs and additional appeals challenging application of the January 2017 Ruling.

Like the 2022 TDL, the purpose of this Ruling is to bring an orderly conclusion to pending (and potentially forthcoming) administrative claims and appeals relating to the requirements for classification, coverage, and payment of CGM claims under Parts B and C. In accordance with section 1871(b)(2)(C) of the Act (42 U.S.C. 1395hh(b)(2)(C)) and the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), there is good cause to issue and apply this Ruling without further public notice-and-comment rulemaking procedures because such procedures are impracticable, unnecessary, and contrary to the public interest in the orderly processing of CGM claims and

administrative appeals under Parts B and C, particularly because the substantive CGM classification, coverage, and payment policies adopted in this Ruling were already subject to notice-and-comment rulemaking in connection with the December 2021 final rule. Moreover, in accordance with section 1871(e)(1)(A)(ii) of the Act (42 U.S.C. 1395hh(e)(1)(A)(ii)), the issuance and retroactive application of this Ruling is necessary to serve the public interest in the orderly processing of CGM claims and administrative appeals under Part B and Part C.

2. Administrative and Judicial Review

Upon receipt of a valid Part B DME claim by a claimant (that is, the patient-beneficiary or their supplier-assignee), the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) issues an initial determination addressing coverage of the item or service and determining any payment due. Section 1869(a)(1), (2) of the Act (42 U.S.C. 1395ff(a)(1) and (2)); 42 CFR 405.904 and 405.920. The claimant then may pursue a multi-level process for administrative and judicial review. First, the appellant (a claimant who has filed an appeal) may request a redetermination by the DME MAC. Section 1869(a)(3) of the Act (42 U.S.C. 1395ff(a)(3)); 42 CFR 405.940. Then the appellant may seek reconsideration by a qualified independent contractor (QIC). Section 1869(b)(1)(A), (c) of the Act (42 U.S.C. 1395ff(b)(1)(A) and (c)); 42 CFR 405.960. Next the appellant may request a hearing before an Administrative Law Judge (ALJ). Sections 205(b) and 1869(b)(1(A) of the Act (42 U.S.C. 405(b) and 1395ff(b)(1)(A)); 42 CFR 405.1002. Then the appellant may request review by the Medicare Appeals Council (the Appeals Council) within the Departmental Appeals Board. Section 1869(d)(2) of the Act (42 U.S.C. 1395ff(d)(2)); 42 CFR 405.1100. The Appeals Council's final decision is subject to judicial review in accordance with sections 205(g) and 1869(b)(1)(A) of the Act (42 U.S.C. 405(g), 1395ff(b)(1)(A)) and 42 CFR 405.1130. If an

appellant does not timely pursue administrative review at any level, then the non-appealed determination or decision becomes final and binding (42 CFR 405.928, 405.958, 405.978, 405.1048, and 405.1130). Final and binding determinations and decisions on Part B claims are subject to reopening if certain criteria are met (42 CFR 405.980).

A similar administrative and judicial review process applies to Part C claims. Upon receipt of a pre-service request for coverage or a valid Part C claim for payment by a claimant (that is, the MA plan enrollee or the provider of the item or service in question), the MAO issues an organization determination addressing coverage of the item or service and determining any payment due. Section 1852(g)(1) of the Act (42 U.S.C. 1395w-22(g)(1)); 42 CFR 422.566(b)(2) and 422.568. The claimant then may pursue a multi-level process for administrative and judicial review if the request is denied or partially denied. To start, the appellant (a claimant who has filed an appeal) may request a reconsideration by the MAO. Section 1852(g)(2) of the Act (42 U.S.C. 1395w-22(g)(2)); 42 CFR 422.578. If the MAO does not rule fully in favor of the appellant in the reconsideration process, it is required to forward the request to an independent entity contracted by CMS for reconsideration. Section 1852(g)(4) of the Act (42 U.S.C. 1395w-22(g)(4)); 42 CFR 422.590 and 422.592. If the independent entity does not rule fully in favor of the appellant, then the appellant may request a hearing before an ALJ. Sections 205(b) and 1852(g)(5)) of the Act (42 U.S.C. 405(b) and 1395w-22(g)(5)); 42 CFR 422.600 and 422.602. The MAO has the right to be a party to this ALJ proceeding (42 CFR 422.602(c)). Next the appellant or, if a party to the ALJ proceeding, the MAO, may request review of the ALJ's decision or dismissal by the Appeals Council (42 CFR 422.608). The Appeals Council's final decision is subject to judicial review in accordance with sections 205(g) and 1852(g)(5) of the Act (42 U.S.C. 405(g) and 1395w-22(g)(5)) and 42 CFR 422.612. Any party to the Appeals

Council's final decision, including the MAO, may request judicial review. *Id.* If an appellant does not timely pursue administrative review at any level, then the non-appealed determination or decision becomes final and binding (42 CFR 422.576 and 422.596). Final and binding organization determinations and decisions on Part C organization determinations are subject to reopening if certain criteria are met (42 CFR 422.616).

IMPLEMENTATION

Implementation of this Ruling involves the following four requirements.

- If a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary on or after the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B or Part C, as applicable, then such claim shall be processed in accordance with the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule. If an enrollee in an MA plan seeks, on or after February 28, 2022, approval of coverage of a CGM prior to receipt of the benefit, then the Part C organization determination shall be decided in accordance with the substantive CGM classification, coverage, and payment policies established in the December 2021 final rule.

- If a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary before the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B or Part C, as applicable, then the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling shall be applied to claims for a CGM monitor or receiver and/or its necessary supplies and accessories where either: (1) a valid CGM claim or valid CGM appeal was pending as of February 28, 2022; or (2) the right to submit a valid CGM

claim or file a valid CGM appeal had not expired as of February 28, 2022. If an enrollee in an MA plan falls in category (1) or (2) of the prior sentence and seeks, before February 28, 2022, approval of coverage of a CGM prior to receipt of the benefit, then any Part C organization determination shall be decided in accordance with the substantive CGM classification, coverage, and payment policies established in the December 2021 final rule and adopted in this Ruling.

- If a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary before the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B or Part C, as applicable, and a non-favorable determination or decision regarding the claim was issued but had not yet become final and binding as of February 28, 2022 (that is, the time to appeal the determination or decision had not yet expired as of February 28, 2022), then such non-final and non-favorable determination or decision shall be reopened for application of the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling.

- If a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary before the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B or Part C, as applicable, and as of February 28, 2022 there was a final and binding determination or decision for such CGM claim and the time to file a valid CGM appeal had expired, then such final and binding determination or decision shall not be reopened for application of the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling.

RULING

First, it is CMS's Ruling that the January 12, 2017 Ruling, CMS-1682-R, is hereby rescinded and shall not be applied to any additional CGM claims under Part B or Part C, as applicable, or to any further administrative appeals of CGM claims.

Second, it is further CMS's Ruling that claims for a CGM monitor or receiver and/or its necessary supplies and accessories under Part B and CGM requests for coverage and claims under Part C, as applicable, shall be controlled by the December 2021 final rule or this Ruling, as applicable, and in any event the following types of CGMs shall be classified as DME: therapeutic or non-adjunctive CGMs; non-therapeutic or adjunctive CGMs; and insulin pumps that also function as a CGM monitor or receiver. However, because smartphones, tablets, or other similar devices that can also function as a CGM monitor or receiver are also useful to an individual in the absence of an illness or injury, and therefore do not meet the definition of DME, such smartphones, tablets, or other similar devices are not classified as DME.

Third, it is also CMS's Ruling that a specific claim for a CGM monitor or receiver and/or its necessary supplies and accessories under Part B or a CGM request for coverage under Part C, as applicable, that is classified as DME under the December 2021 final rule or this Ruling, shall be covered under Part B or Part C, as applicable, provided that the specific CGM is determined to be reasonable and necessary for diagnosis or treatment of illness or injury for the Medicare patient-beneficiary. If a Medicare beneficiary is using a smartphone or other similar non-DME device to display their glucose readings in conjunction with the DME item, then the disposable items (but not the smartphone or other similar non-DME item) shall be covered under Part B or Part C, as applicable, because the beneficiary is using the DME item as the primary device to display their glucose readings, again provided that the specific DME item is determined to be

reasonable and necessary for diagnosis or treatment of illness or injury for the Medicare beneficiary.

Fourth, it is further CMS's Ruling that if a specific CGM monitor or receiver and/or its necessary supplies and accessories qualifies for coverage under Part B or Part C, as applicable, under the December 2021 final rule or this Ruling, then the pertinent claim shall be paid in accordance with the fee schedule payment policies addressed in the December 2021 final rule and adopted in this Ruling.

Fifth, it is also CMS's Ruling that if a non-final, non-binding, and non-favorable determination or decision on a claim for a CGM monitor or receiver and/or its necessary supplies and accessories under Part B or Part C, as applicable, was pending in a valid administrative appeal as of February 28, 2022, then the pertinent administrative appeal tribunal shall issue a determination or decision based on this Ruling. Effectuation of such determination or decision shall be performed by the DME MAC (for Part B claims) or the MAO (for Part C claims), as applicable, and the underlying claims shall be adjusted in accordance with the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling.

Sixth, it is further CMS's Ruling that if, as of February 28, 2022, a non-final, non-binding, and non-favorable determination or decision on a claim for a CGM monitor or receiver and/or its necessary supplies and accessories under Part B or Part C, as applicable, has not yet been appealed but the period for filing a valid appeal had not yet expired as of February 28, 2022, then whomever rendered such determination or decision shall reopen its determination or decision and issue a new determination or decision based on this Ruling. Effectuation of the new determination or decision shall be performed by the DME MAC (for Part B claims) or the MAO

(for Part C claims), as applicable, and the underlying claims shall be adjusted in accordance with the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling.

Seventh, it is also CMS's Ruling that, consistent with 42 CFR 405.986(b) and 422.616(a), this Ruling is not an appropriate basis for the reopening of any payment determination or decision regarding a CGM monitor or receiver and/or its necessary supplies and accessories under Part B or Part C, as applicable, except as set forth in the third bulleted paragraph of the Implementation section of this Ruling, and directly above in the sixth paragraph of this Ruling section.

Eighth, it is further CMS's Ruling that in accordance with section 1871(b)(2)(C) of the Act (42 U.S.C. 1395hh(b)(2)(C)) and the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), there is good cause to issue and apply this Ruling without further public notice-and-comment rulemaking procedures because such procedures are impracticable, unnecessary, and contrary to the public interest in the orderly processing of CGM claims and administrative appeals under Part B and Part C. CMS notes that the substantive CGM classification, coverage, and payment policies underlying this Ruling were already subject to notice-and-comment rulemaking in connection with the December 2021 final rule, and CMS is adopting those policies here for similar reasons as those described in the December 2021 final rule.

Ninth, it is also CMS's Ruling that in accordance with section 1871(e)(1)(A)(ii) of the Act (42 U.S.C. 1395hh(e)(1)(A)(ii)), the issuance and retroactive application of this Ruling is necessary to serve the public interest in the orderly processing of CGM claims and administrative appeals under Part B and Part C.

Tenth, it is also CMS's Ruling that this Ruling shall be implemented in accordance with the four requirements set forth in the Implementation section of this Ruling.

CMS-1738-R

EFFECTIVE DATE

This Ruling is effective May 13, 2022. **[Insert date]**

Dated: May 13, 2022 **[Insert date]**

Chiquita Brooks-LaSure,
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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary, United States Department of Health and Human Services,

Defendant.

No. 2:21-CV-00326-SMJ

DECLARATION OF LINDA KEYSER

I, Linda Keyser, hereby declare as follows:

1. I am over the age of 18 and competent to testify herein. I have personal knowledge of the facts set forth below.

2. I am an attorney in the Office of the General Counsel ("OGC") within the Department of Health and Human Services ("HHS"). One of my responsibilities in this role is to serve as "agency counsel" for the Centers for Medicare & Medicaid Services ("CMS"), which is a component of HHS, in litigation filed in federal court. As agency counsel, I interface with attorneys from the Department of Justice, who

themselves appear as counsel of record, and sometimes appear as counsel of record along with them.

3. I am presently serving as agency counsel for CMS in this action. I also served as agency counsel for CMS in a prior action captioned *Olsen v. Becerra*, No. 20-CV-00374-SMJ (E.D. Wash.) ("*Olsen I*"), involving the same plaintiff-beneficiary. I have not appeared as counsel of record in either this action or *Olsen I*.

4. CMS is the component of HHS responsible for administering the Medicare program.

5. Noridian Healthcare Solutions ("Noridian") is the Medicare Administrative Contractor for the jurisdiction that includes the Eastern District of Washington. A Medicare Administrative Contractor is a private health care insurer that has been awarded a geographic jurisdiction within which to process Medicare Part A and Part B medical claims or durable medical equipment claims for Medicare fee-for-service beneficiaries.

6. On February 23, 2021, this Court entered its Order Granting Plaintiff's Motion for Summary Judgment and Denying Defendant's Cross Motion for Summary Judgment in *Olsen I*. *Olsen v. Becerra*, 2021 WL 711469, No. 20-CV-00374-SMJ, at *4 (E.D. Wash., Feb. 23, 2021). The Court concluded, in sum, that Plaintiff's Continuous Glucose Monitor ("CGM") device constitutes durable medical equipment, and that the agency erred in denying Plaintiff's Medicare claim for coverage of supplies related to his CGM device. *Id*.

7. Neither I nor CMS promptly ensured that Noridian and the various entities responsible for handling administrative appeals above Noridian (the Qualified Independent Contractor (the "QIC"), the Administrative Law Judges ("ALJs"), and the Medicare Appeals Council ("the Council")) would be granting all of Plaintiff's CGM claims and pending appeals going forward in light of the Court's decision in *Olsen I*. This was an inadvertent oversight.

8. On April 16, 2021, Noridian denied Plaintiff's March 10, 2021, CGM claim, which is one of the two claims at issue in this action. Based upon my conversations with Noridian representatives, it is my understanding that this claim was denied because Noridian was unaware at that time of this Court's February 23, 2021, decision in *Olsen I*, which was favorable to Plaintiff.

9. On July 13, 2021, I contacted CMS, attaching the *Olsen I* complaint and this Court's February 23, 2021, decision in *Olsen I*, and asked it "to instruct the contractor (Eastern District of Washington) to pay the claim ASAP and also to implement a system to pay all CGM-related claims for this beneficiary going forward." CMS contacted the CMS Contracting Officer's Representative ("COR") for Noridian the same day with instructions to "ensure these claims are paid."

10. Also on July 13, 2021, the COR emailed Noridian directing that it "pay the claim as soon as possible and implement a system to pay all CGM-related claims for this beneficiary going forward."

11. At the time of the February 23, 2021, decision in *Olsen I*, Plaintiff had pending before the Council an April 19-June 18, 2019, CGM claim that had been denied by the ALJ on January 31, 2020; that claim is one of the two claims at issue in this action. On October 22, 2021, the Council upheld the ALJ's denial of Plaintiff's April 19-June 18, 2019, CGM claim. Based upon my conversations with HHS employees who oversee the administrative appeals processes before the ALJs and the Council, it is my understanding that the Council upheld the ALJ's denial because it was unaware of this Court's February 23, 2021, decision in *Olsen I*, which was favorable to Plaintiff. While CMS and Noridian had been made aware of this Court's February 23, 2021, *Olsen I* decision, that information was apparently not provided to the various entities responsible for handling administrative appeals above Noridian (the QIC, the ALJs, and the Council).

12. On November 18, 2021, Plaintiff filed this action, challenging the denial of his April 19-June 18, 2019, and March 10, 2021, CGM claims. *See* Compl. ¶ ¶ 61-90, ECF No. 1 at 14-19.

13. On December 22, 2021, in response to an inquiry from OGC and CMS about the ongoing denial of Plaintiff's CGM claims, Noridian reported via email as follows:

> I reviewed this beneficiary's claim history. All the claims from your original July communication were reprocessed correctly.
>
> However, a new claim (CCN 21288839976001) was submitted for the sensors for service date 10-13-2021 for $1824.90 and was incorrectly

> denied. At the time of your original July email, I had a flag added to this beneficiary's file to suspend any claims for these sensors. I did this because the VMS system is hard coded to deny this HCPCS A9276. This code is non-covered; however, we have been instructed in certain cases to pay this code when CMS advises us due to a court order.
>
> The claims associate should have changed the submitted code to a "not otherwise classified" code to allow it to be manually allowed and processed. Unfortunately, she did not change the code, and the system denied the claim. The associate has been re-educated on the need to change the code in this unique situation.

I misconstrued this information to also apply to the April 19-June 18, 2019, and March 10, 2021, CGM claims at issue in this action, *see* ¶ 12 supra, and reported the same to the United States Attorneys' Office for the Eastern District of Washington, which, in turn, incorporated that information into Defendant's Answer to the Complaint. *See* Def.'s Answer to Compl., ¶ 3, ECF No. 4 at 3.

14. OGC has reached out directly to CMS, Noridian, and the entities handling each level of administrative appeal (the QIC, the ALJs, and the Council) to ensure payment of Plaintiff's CGM-related claims going forward.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the above statements are true and correct.

DATED: April 19, 2022

Respectfully submitted,

/s/ Linda Keyser
Linda Keyser
Litigation Attorney
U.S. Department of Health and Human Services
Office of the General Counsel
Center for Medicare & Medicaid Services Division

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE

TDL-220257

MEMORANDUM

DATE: February 25, 2022

FROM: Contracting Officer's Representatives (CORs)
Medicare Administrative Contractors, Center for Medicare

Director, Technology, Coding and Pricing Group
Center for Medicare

Director, Medicare Enrollment & Appeals Group
Center for Medicare

Director, Medicare Contractor Management Group
Center for Medicare

SUBJECT: Medicare Benefit Policy Classification and Payment for Continuous Glucose Monitors (CGMs)

TO: All Medicare Administrative Contractors (MACs)

This Technical Direction Letter (TDL) provides instructions to the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) regarding Medicare benefit policy classification and payment for continuous glucose monitors (CGMs). The Centers for Medicare & Medicaid Services (CMS) published a final rule on December 28, 2021 that addresses classification and payment for CGMs under the Medicare Part B benefit for durable medical equipment (DME). *See* 86 Fed. Reg. 73,860, 73,896–73,902 (Dec. 28, 2021) ("2021 final rule"). The 2021 final rule is effective on February 28, 2022, and thus applies to claims for a CGM monitor or receiver and/or its necessary supplies and accessories that are supplied to a Medicare beneficiary on or after February 28, 2022. This TDL is effective on February 28, 2022.

The 2021 final rule replaced a 2017 CMS Ruling, CMS-1682-R ("2017 Ruling"), regarding CGMs. Pursuant to this TDL, the DME MACs shall apply the coverage and payment provisions of the 2021 final rule to valid reimbursement claims and appeals for CGM monitors or receivers

and/or necessary supplies and accessories supplied prior to February 28, 2022. The 2021 final rule obviates the need for further application of the 2017 Ruling on CGMs, as CMS has determined that, in addition to therapeutic or non-adjunctive CGMs, non-therapeutic or adjunctive CGMs can also meet the Medicare definition of durable medical equipment (DME) at 42 C.F.R. § 414.402. Applying the coverage and payment provisions of the 2021 final rule to valid reimbursement claims and appeals for CGM monitors or receivers and/or necessary supplies and accessories supplied prior to February 28, 2022 will avoid expending administrative resources on further application of the 2017 Ruling on CGMs and additional appeals challenging application of the 2017 Ruling.

For valid claims and appeals covered by this TDL, both therapeutic or non-adjunctive CGMs and non-therapeutic or adjunctive CGMs shall be considered DME by the DME MACs pursuant to this TDL if the CGM's monitor or receiver satisfies the definition of DME in 42 C.F.R. § 414.202. This includes CGM monitors and receivers that are incorporated into insulin infusion pumps, which as the 2021 final rule indicates should not have been denied based on the 2017 Ruling in any event. If a specific CGM monitor or receiver is classified and covered as DME, or the CGM monitor or receiver is incorporated into an insulin infusion pump, then the CGM sensors and transmitters used in conjunction with the CGM monitor or receiver shall also fall under the DME benefit if they are determined to be supplies and accessories necessary for the effective use of the CGM. Coverage of a specific CGM monitor or receiver and/or its necessary supplies or accessories shall still also require a determination that the CGM is found to be medically reasonable and necessary for the diagnosis or treatment of an illness or injury for the beneficiary.

Pursuant to this TDL, if a therapeutic or non-adjunctive CGM is classified and covered as DME or the monitor or receiver is part of a covered insulin infusion pump and the CGM monitor or receiver is medically reasonable and necessary, then the CGM monitor or receiver and/or its necessary supplies and accessories shall be paid in accordance with the appropriate fee schedule amounts. If a non-therapeutic or adjunctive CGM is classified and covered as DME or the monitor or receiver is part of a covered insulin infusion pump and the CGM monitor or receiver is medically reasonable and necessary, then the CGM monitor or receiver and/or the supplies and accessories necessary for the effective use of the CGM monitor or receiver shall be paid in accordance with fee schedule amounts established in accordance with 42 C.F.R. § 414.238 and the fee schedule gap-filling instructions in section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

The DME MACs shall apply the direction in this TDL to CGM monitors or receivers and/or their necessary supplies and accessories supplied to a beneficiary before the February 28, 2022 effective date of the 2021 final rule where either (1) a valid reimbursement claim or valid appeal is pending as of February 28, 2022; or (2) the right to submit a valid reimbursement claim or file a valid appeal has not expired as of February 28, 2022.

More specifically, DME MACs shall apply the instructions in this TDL to valid CGM reimbursement claims and appeals: (1) that were open (i.e., non-final) as of February 28, 2022, if the timeframe to file a valid appeal has not expired before that date; or (2) that are submitted after February 28, 2022 for CGM monitors or receivers and/or their necessary supplies and accessories supplied before February 28, 2022, so long as the claim or appeal is submitted timely and in accordance with all procedural requirements. For example, if an initial determination on a CGM claim was issued before February 28, 2022, and the 120-day period for requesting redetermination has not expired before that date, then this TDL shall be applied to that claim.

However, this TDL shall not be applied to CGM reimbursement claims that were final and binding before February 28, 2022 and the right to file a valid appeal has expired before that date. For example, if an initial determination on a CGM claim was issued but the 120-day period for requesting redetermination has expired before February 28, 2022, then this TDL shall not be applied to that claim. In any event, CGM reimbursement claims for CGM monitors or receivers and/or their necessary supplies and accessories supplied on or after February 28, 2022 are covered directly by the 2021 final rule.

In order to conserve administrative resources and further the interests of administrative finality, this TDL shall not serve as a basis for reopening a determination or decision regarding a CGM reimbursement claim that was final and binding and no longer subject to appeal before the February 28, 2022 effective date of the 2021 final rule and this TDL.

DME MACs shall review CGM reimbursement claims previously denied and determine if the claims were valid or any appeal was valid as of the February 28, 2022 effective date of this TDL. For CGM claims appealed to the qualified independent contractor (QIC), the DME MACs shall provide a spreadsheet with a list of CGM claims pending at the QIC that might be eligible for coverage under the foregoing provisions of this TDL. CMS will issue instructions to the QIC for handling CGM claims and appeals pending at the QIC.

Provider Education

No national message will be distributed from CMS.

Local contractor messaging about this TDL is prohibited.

DME MAC Contract Numbers

Jurisdiction A ~ HHSM-500-2016-M0001Z
Jurisdiction B ~ HHSM-500-2015-M0030Z
Jurisdiction C ~ 75FCMC20C0025
Jurisdiction D ~ HHSM-500-2015-M0031Z

This Technical Direction Letter (TDL) is being issued to you as technical direction under your MAC contract and has been approved by your Contracting Officer's Representative (COR). This technical direction is not to be construed as a change or intent to change the scope of work under the contract and is to be acted upon only if sufficient funds are available. In this regard, your attention is directed to the clause of the General Provisions of your contract entitled Limitation of Funds, FAR 52.232-22 or Limitation of Cost, FAR 52.232-20 (as applicable). If the Contractor considers anything contained herein to be outside of the current scope of the contract, or contrary to any of its terms or conditions, the Contractor shall immediately notify the Contracting Officer in writing as to the specific discrepancies and any proposed corrective action.

Unless otherwise specified, contractors shall be in compliance with this TDL within 10 business days from its date of issuance.

Should you require further technical clarification, you may contact your COR. Contractual questions should be directed to your CMS Contracting Officer. Please copy the COR and Contracting Officer on all electronic and/or written correspondence in relation to this technical direction letter.

/s/
Pam Durbin, JA DME MAC COR
Lisa Laubach, JB DME MAC COR
Lisa Laubach, JC DME MAC COR
Pam Durbin, JD DME MAC COR

/s/
Jason Bennett
Jerry Mulcahy (he, him)
Larry Young

cc:
Don Via, CGS Administrators, LLC
James Doane, CGS Administrators, LLC
Melissa Kirchenbauer, CGS Administrators, LLC
Becky Kuznia, Noridian Healthcare Solutions, LLC
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Tara Odden, Noridian Healthcare Solutions, LLC
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Martin Furman, CM/MCMG
Pam Durbin, CM/MCMG
Torris Smith, CM/MCMG

Karen Jacobs, CM/TCPG/DDP
All RAs, CMS
Maria Ramirez, CPC/MEAG/DAO
Alyssa Jones, OAGM
Cheryl Caldwell, OAGM
Edward B. Farmer, OAGM
Jeannine Bohlen, OAGM
Juanita Wilson, OAGM
Lauren Holsey, OAGM
Mark Werder, OAGM
Mohammed Islam, OAGM
Gregory Dill, OPOLE – IFM
Linda Keyser, HHS OGC
Gerard Keating, HHS OGC
Susan Lyons, HHS OGC

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, Defendant	No. COMPLAINT FOR ADMINISTRATIVE REVIEW, DECLARATORY RELIEF, INJUNCTIVE RELIEF, AND APPOINTMENT OF A SPECIAL MASTER JURY TRIAL DEMANDED

1. Plaintiff Mr. Jeremy Olsen brings this action against Defendant Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services. Plaintiff makes the following allegations based on the investigation of counsel and on information and on personal knowledge.

I. INTRODUCTION

2. This litigation is the result of the Secretary's continued bad faith in considering claims for continuous glucose monitor (CGM)

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coverage. Mr. Olsen previously filed suit in this Court and obtained a judgment ordering coverage of his CGM claims. *See Olsen v. Becerra*, E.D. Wa. Case No. 20-cv-374 (SMJ) (hereinafter, "*Olsen I*"). This Court further found that the Secretary's base position (*i.e.*, that a CGM is not "primarily and customarily used to serve a medical purpose") was frivolous and in "bad faith." Further, the Court determined that the Secretary had engaged in bad faith and vexatiousness during the course of the litigation. As a result (on information and belief), for only the eleventh time in the past 10 years,[1] the United States was found to have engaged in "bad faith" and this Court awarded attorneys fees at market rates to Plaintiff. *Id*. at Dkt. #50 (April 20, 2021).

3. Incredibly, *after* this Court's "bad faith" finding, the Secretary has continued to reject CGM claims, including Mr. Olsen's claims, on the same "bad faith" grounds (*i.e.*, that a CGM is not "primarily and customarily used to serve a medical purpose" as construed in CMS 1682-R or standing alone).

[1] Based on investigation of counsel, during this period, the United States was a party to well more than one million cases.

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4. In addition to the basic continued denial of Mr. Olsen's claims on the "bad faith" grounds, the Secretary has also engaged in "bad faith" in an effort to delay/avoid judicial review. In particular, in defiance of Congress' intent, the Secretary (through his appointees, the Departmental Appeals Board) in "bad faith" denied Mr. Olsen's request for "expedited access to judicial review" on the grounds that something other than illegally issued CMS 1682-R barred coverage, when the only basis for denial was CMS 1682-R and an ALJ had already ruled that *only* CMS 1682-R barred coverage of the claim at issue.

5. Thus, the Secretary sought to prolong the "bad faith" process and subject Mr. Olsen to increased delay and expense through his "bad faith" handling of Mr. Olsen's claims.

6. Because of the repeated instances of "bad faith" conduct, this suit seeks to have Mr. Olsen's claims covered, set aside CMS 1682-R and enjoin its use to reject CGM claims, and place CGM claims denials under this Court's supervision through a special master for a limited period of time until the Court is satisfied that the Secretary will not engage in "bad faith" conduct in considering such claims and jeopardizing the lives of beneficiaries.

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II. JURISDICTION

7. This Court has jurisdiction over this action pursuant to 42 U.S.C. §§ 405(g) and 1395ff. Mr. Olsen is filing suit after a final decision(s) of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of his Medicare claim (and, therefore, has exhausted his administrative remedies), the amount-in-controversy is more than $1,600 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decision.

8. In addition, for one of the claims at issue, jurisdiction over this action is proper pursuant to 42 U.S.C. §§ 405(g) and 1395ff because Plaintiff has presented his claim, had been denied, and further process would be futile. Alternatively, for that same claim, jurisdiction is proper under 42 U.S.C. § 1395ff(b)(2) because Plaintiff utilized the expedited access to judicial review procedure and the Secretary did not issue a decision by a neutral decision maker within 60 days.

9. Venue is proper in this district pursuant to 42 U.S.C. § 405(g) and 42 U.S.C. § 1395ff(b)(2)(c)(iii) because this action is being brought in the Eastern District of Washington.

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III. PARTIES

10. Plaintiff Jeremy Olsen is an individual and a resident of the State of Washington. Mr. Olsen is eligible for Medicare on the basis of disability as previously determined by the Secretary.

11. Defendant Xavier Becerra sued in his official capacity as the Secretary of Health and Human Services.

IV. FACTUAL BACKGROUND

12. In the interests of brevity, Plaintiff will not repeat general information/allegations regarding diabetes and the Medicare appeals process. For this information, Plaintiff refers the Court to the prior case: *Olsen v. Azar*, E.D. Wa., Case No. 20-cv-374 (SMJ).

A. Durable Medical Equipment

13. Medicare covers "durable medical equipment." Pursuant to 42 U.S.C. § 1395x(n), "durable medical equipment" is not defined, except by example.

14. One such example is "glucose monitors."

15. The Secretary has issued regulations further setting forth a five-part test to determine whether equipment is "durable medical equipment" within the meaning of § 1395x(n) (see 42 C.F.R. § 404.202).

16. Equipment is considered "durable medical equipment" if it:

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a) Can withstand repeated use;
b) Has an expected life of at least 3 years;
c) Is primarily and customarily used to serve a medical purpose;
d) Generally is not useful to an individual in the absence of illness or injury; and
e) Is appropriate for use in the home.

B. CMS-1682-R

17. Pursuant to 42 U.S.C. § 1395hh(2):

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

18. The "paragraph (1)" referred to requires "notice and comment" as described in the remainder of 42 U.S.C. § 1395hh.

19. Without notice and comment, on January 12, 2017, CMS issued Ruling No. CMS-1682-R as CMS "final opinion and order" with regard to CGM coverage.

20. By its own terms, that Ruling is "binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration …"

21. The Ruling addresses whether CGMs are DME and, therefore, covered within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

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22. As set forth there, if a CGM does not completely replace finger prick/test strips, CMS considers the device not "primarily and customarily used to serve a medical purpose." This is so, CMS contends, because patients do not "mak[e] diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM[.]" *See* CMS-1682-R at 6-7. CMS calls these CGM's "non-therapeutic."

23. The Ruling determines that one CGM that has been FDA approved to completely replace finger pricks/test strips is DME (the Dexcom G5). *See* CMS-1682-R at 7-10. In particular, the Ruling determines that the receiver/monitor portion of a CGM lasts more than 3 years and, including other factors, that the whole system is DME within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

24. Both before and after issuance of CMS-1682-R, the Secretary has refused coverage of CGM devices made by Medtronic and Dexcom (other than the Dexcom G5) on the grounds that they are not "primarily and customarily used to serve a medical purpose."

25. Further, as a result of CMS-1682-R, the discretion ALJ's previously had to award coverage (even in the face of an alleged LCD) was eliminated. As a result, it is futile to submit claims for non-Dexcom G5

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devices with dates of service after January 12, 2017. Because the ALJs no longer have discretion, those claims must be denied.

26. Without notice and comment, CMS-1682-R was subsequently incorporated into LCD L33822.

27. Without notice and comment, CMS-1682-R was subsequently incorporated into Policy Article A52464.

28. Thus, the Ruling substituted the non-statutory/regulatory term "therapeutic" for the previous non-statutory/regulatory term "precautionary" as the criteria/basis for denials.

29. ALJs are bound by CMS Rulings and cannot determine that CMS Rulings are invalid.

30. The Medicare Appeals Council (MAC) is bound by CMS Rulings and cannot determine that CMS Rulings are invalid.

31. Each month, approximately 13,000 claims for CGM coverage (under both Medicare Part B and Part C) are denied on the basis of CMS 1682-R.

C. Other Litigation Related to CGMs

32. In general, the Secretary has refused to cover CGMs on the grounds that a CGM is not durable medical equipment. This is so, the

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Secretary contends, because CGMs are not "primarily and customarily used to serve a medical purpose."

33. Instead, the Secretary contends that a CGM is excluded from coverage as "precautionary" – a non-statutory term. Although there was no national or local coverage determination (NCD/LCD) excluding CGM coverage, a local coverage article (LCA) described CGMs as excluded as "precautionary." LCA A52464.

34. The Secretary's refusal to cover CGMs has been the subject of numerous litigations.

35. At the Medicare Administrative Law Judge ("ALJ") level, for claims not subject to CMS 1682-R, more than 40 ALJs considered the Secretary's position that a CGM is not "primarily and customarily used to serve a medical purpose" and rejected that claim more than 55 times. A listing of relevant ALJ decisions may be found at http://dparrishlaw.com/wp-content/uploads/2017/11/Favorable-ALJs-on-CGM2.pdf.

36. As to the Secretary's base position that a CGM is not "primarily and customarily used to serve a medical purpose", that position has been rejected by four district courts (not counting this one).

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37. In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.), *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.), and *Zieroth v. Azar*, 2020 WL 5642614 (N.D. Ca. Sept. 22, 2020), the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose" was erroneous, not supported by substantial evidence, and in each case, ordered the Secretary to provide CGM coverage.

38. Further, in the *Whitcomb* case, the court found that the Secretary's position was "arbitrary and capricious" and "unreasonable." Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.) at 14, 12.

39. In addition, all four courts found that the Secretary's position lacked "substantial justification" and awarded attorney's fees to the plaintiffs pursuant to the Equal Access to Justice Act. *See* 5 U.S.C. § 504.

40. Likewise, the Secretary's own Civil Remedies Division concluded that exclusion of CGM coverage on the grounds that a CGM is "precautionary" did not pass the "reasonableness standard." *See* DAB No. CR4596, 2016 WL 2851236 at *18.

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D. Facts Specific to Mr. Olsen

41. Jeremy Olsen is a 43-year old father of three and a journeyman carpenter. In his free time, Mr. Olsen enjoys fixing up old cars, woodworking, and crafts activities.

42. First diagnosed with Type I diabetes at the age of nine (9), Mr. Olsen is a "brittle" diabetic (*i.e.*, his glucose levels are prone to wild and rapid swings). In addition, Mr. Olsen suffers from hypo/hyperglycemic unawareness (*i.e.*, he has no physical sensations – head aches, sweats, etc. – that alert him his glucose levels need to be adjusted). Prior to receiving an insulin pump and a CGM, Mr. Olsen had to be revived at the Emergency Room more than 20 times because of his uncontrolled diabetic condition.

43. To assist with management of his diabetes, Mr. Olsen was fitted with an insulin pump.

44. As a result of his diabetic condition, Mr. Olsen suffered from kidney failure. In 2016, Mr. Olsen had kidney and pancreas transplant surgery. While it was hoped that the pancreas transplant would address Mr. Olsen's diabetes, the transplant did not succeed and Mr. Olsen continues to suffer from diabetes.

45. In 2018, Mr. Olsen was prescribed a Medtronic MiniMed continuous glucose monitor for two reasons. First, of course, given his

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brittle diabetes and hypoglycemic unawareness, traditional finger stick checking was not sufficient to manage Mr. Olsen's diabetes such that he continued to suffer a risk of death and other complications. Second, out of range glucose levels as a result of the diabetes jeopardize Mr. Olsen's transplanted kidney.

46. The Medtronic MiniMed CGM communicates with Mr. Olsen's insulin pump to properly regulate the amount of insulin being dispensed. Since receiving an insulin pump and the CGM which interfaces with it, Mr. Olsen has not had to visit the Emergency Room as a result of his diabetic condition.

47. As a result of his diabetic condition, Mr. Olsen receives Social Security disability benefits.

48. Mr. Olsen is enrolled in Medicare Part B and, each month, Medicare premiums in the amount of $148.50 are deducted from Mr. Olsen's Social Security disability benefits.

49. As a result of Mr. Olsen's payment of the Medicare premiums and enrollment in Medicare Part B, Mr. Olsen is "entitled" to Medicare payment for qualifying claims.

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E. Prior Litigation Before This Court

50. The Secretary has previously denied Mr. Olsen's claims for CGM coverage on the grounds that Mr. Olsen's CGM is not "primarily and customarily used to serve a medical purpose."

51. On December 23, 2019, Olsen filed suit after the Secretary issued a final decision denying a claim for coverage.

52. That suit was subsequently transferred to this Court and was styled *Olsen v. Becerra*, E.D. Wa., Case No. 20-cv-374 (SMJ).

53. There, Mr. Olsen sought a reversal of the Secretary's denial, a remand ordering coverage, a declaration that CMS 1682-R issued illegally, and that the Court set aside CMS 1682-R.

54. The parties filed cross-motions for summary judgment.

55. On February 23, 2021, this Court denied the Secretary's motion(s) for summary judgment and granted judgment in Mr. Olsen's favor, finding that a CGM is "primarily and customarily used to serve a medical purpose" and covered "durable medical equipment."

56. The Court's judgment did not address the issue of the illegal issuance of CMS 1682-R.

57. Thereafter, on April 20, 2021, this Court granted Mr. Olsen's requests for attorney's fees.

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58. In particular, the Court found that the Secretary's position that a CGM is not "primarily and customarily used to serve a medical purpose" was frivolous and in bad faith.

59. In addition, the Court found that the Secretary's representative (Mr. Bickford) had also engaged in bad faith mischaracterizations in attempting to switch the bases for denial of Mr. Olsen's claims.

60. The Court awarded "bad faith" attorney's fees pursuant to 28 U.S.C. § 2412(b) at market rates in an amount in excess of $68,000.

V. The Claims at Issue in this Case

61. This case relates to two claims for CGM coverage submitted by Mr. Olsen denied on the same "bad faith" grounds as was the subject of the prior case before this Court (hereinafter, "*Olsen I*").

62. In addition, the Secretary's conduct (including efforts to evade and/or delay judicial review) in considering Mr. Olsen's claims after *Olsen I* were also in bad faith, separately constitute additional breaches of the law, and demonstrate that the Secretary in not a neutral decision maker in considering CGM claims.

A. April 19 – July 18, 2019 Claim – ALJ Appeal No. 3-8946502107/M-20-1269

63. For the period April 19 – July 18, 2019, Mr. Olsen received a 90 day supply of sensors for use with his CGM.

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64. Mr. Olsen's claim was rejected initially, on redetermination, on reconsideration, and by an ALJ in a decision dated January 31, 2020 all on the "bad faith" grounds.

65. Mr. Olsen timely appealed to the MAC.

66. On October 22, 2021, the MAC issued a decision denying Mr. Olsen's claim, again, on the "bad faith" grounds.

B. March 10, 2021 Claim – ALJ Appeal No. 3-10205345873

67. On March 10, 2021, Mr. Olsen received a 90-day supply of sensors for use with his CGM.

68. The amount of the claim was $1,824.90.

69. Mr. Olsen's claim for coverage was rejected initially on the "bad faith" grounds and no other.

70. Mr. Olsen's claim for coverage was rejected on redetermination on the "bad faith" grounds and no other.

71. Mr. Olsen sought reconsideration on the grounds that CMS 1682-R issued illegally and could not be used to deny his claim.

72. On August 24, 2021, Mr. Olsen's claim for coverage was rejected on reconsideration on the "bad faith" grounds and no other.

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73. As a result of the continued denial of his claims on the "bad faith" grounds, Mr. Olsen retained an attorney to re-litigate the issues already determined by this Court.

74. Pursuant to 42 U.S.C. § 1395ff(b)(2) and 42 C.F.R. § 405.990, Mr. Olsen sought to utilize the "expedited access to judicial review procedure."

75. Thus, Mr. Olsen responded to the denial of his request for reconsideration by contemporaneously filing a request for ALJ review (September 7, 2021) and a request for "expedited access to judicial review" with the Departmental Appeals Board (DAB) (September 8, 2021).

76. On October 1, 2021, Mr. Olsen received a "Medicare Summary Notice" (MSN) indicating Medicare's intention to pay some 13 CGM claims submitted by Mr. Olsen going back more than 3 years, including claim denials that Mr. Olsen failed (though inadvertence) to appeal.

77. Included on the October 1, 2021, MSN were the claims at issue in this case.

78. Pursuant to 42 C.F.R. § 405.352, if the Secretary determines that he has overpaid a claim, the Secretary can recoup overpayments by deducting monies from government benefits otherwise due the beneficiary, including Social Security disability benefits.

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1. October 30, 2021, Decision of ALJ Jason Earnhart

79. On September 7, 2021, through his counsel, Mr. Olsen filed a request for ALJ review limited solely to the issue of whether the "bad faith" denial was proper because CMS 1682-R issued illegally.

80. On October 8, 2021, ALJ Jason Earnhart held a hearing, where Mr. Olsen was represented by counsel.

81. On October 30, 2021, ALJ Earnhart issued a decision denying Mr. Olsen's claim.

82. ALJ Earnhart held that a CGM is "medically necessary" for Mr. Olsen's condition.

83. Nevertheless, ALJ Earnhart also held that he was "bound by CMS 1682-R to find that" Mr. Olsen's CGM was non-covered.

84. ALJ Earnhart noted that items not falling within CMS 1682-R's construction of "primarily and customarily used to serve a medical purpose" are ascribed certain codes, including A9276 (sensors), A9277 (transmitter), and A9278 (receiver).[2]

[2] While not the subject to this suit at this time, Plaintiff notes that he submitted a claim for his regular three-month supply of sensors received on October 15, 2021. On November 11, 2021, Mr. Olsen received a notice

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85. Accordingly, based solely on CMS 1682-R, ALJ Earnhart denied coverage.

2. November 2, 2021 Departmental Appeals Board Decision

86. On September 8, 2021, through his counsel, Mr. Olsen sought "expedited access to judicial review."

87. There, Mr. Olsen noted that the only basis for denial of his claim through reconsideration was the illegally issued CMS 1682-R and that ALJs and the MAC are bound by CMS Rulings and cannot find them invalid.

88. On November 2, 2021, the Appellate Division of the Departmental Review Board (DAB) issued a decision denying Mr. Olsen's request for Expedited Access to Judicial Review, pursuant to 42 U.S.C. § 1395ff(b)(2).

89. There, the DAB held that because there might be some other, unasserted, grounds on which Mr. Olsen's claim might be denied, Mr.

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indicating that his sensors had been coded A9276 (i.e., categorized as not "durable medical equipment") and also indicating that there was no documentation that Mr. Olsen needed his regular three-month supply of sensors.

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Olsen could not establish that "but for" the illegal CMS 1682-R, Mr. Olsen's claim would be approved.

90. The DAB decision did not reference the prior decision of ALJ Earnhart or identify any basis, other than CMS 1682-R, on which Mr. Olsen's claim had been rejected.

VI. CAUSES OF ACTION

COUNT I
Violation of 5 U.S.C. § 706(1)
(unlawfully withheld or unreasonably delayed)

91. Paragraphs 1-90 are incorporated by reference as if fully set forth herein.

92. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

93. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

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COUNT II
Violation of 5 U.S.C § 706(2)(A)
(arbitrary and capricious, abuse of discretion, not in accordance with law)

94. Paragraphs 1-90 are incorporated by reference as if fully set forth herein.

95. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

96. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III
Violation of 5 U.S.C § 706(2)(C)
(in excess of statutory jurisdiction, authority, or limitations or short of statutory right)

97. Paragraphs 1-90 are incorporated by reference as if fully set forth herein.

98. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related

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supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

99. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as in excess of the Secretary's authority and limitations and short of Plaintiffs' statutory rights and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT IV
Violation of 5 U.S.C § 706(2)(D)
(without observance of procedure required by law)

100. Paragraphs 1-90 are incorporated by reference as if fully set forth herein.

101. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

102. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as done without observance of the procedure required by law (e.g., notice and comment required for modification of LCDs) and issue an order finding that a CGM and its related supplies covered durable

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medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT V
Violation of 5 U.S.C § 706(2)(E)
(not supported by substantial evidence)

103. Paragraphs 1-90 are incorporated by reference as if fully set forth herein.

104. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

105. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as not supported by substantial evidence and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT VI
Deprivation of Property Interest in Without Procedural and Substantive Due Process Under the United States Constitution

106. Paragraphs 1-90 are incorporated by reference as if fully set forth herein.

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107. Pursuant to the Fifth and Fourteenth Amendments to the Constitution of the United States, Mr. Olsen has a right not to be "deprived of life, liberty, or property without due process of law."

108. As a result of his payment of Medicare premiums, Mr. Olsen has a Constitutionally protected property interest in funds due as a result of qualifying claims submitted to Medicare.

109. Mr. Olsen has been deprived his property interest in this regard without due process because the Secretary has not appointed a neutral decision maker to consider Mr. Olsen's claims.

110. The decisions of the ALJs and the MAC are controlled by the Secretary's "bad faith" policy.

111. The decision of the Departmental Appeals Board with regard to "expedited access to judicial review" is in "bad faith" and not reflective of a neutral decision maker.

112. Thus, the decisions denying Mr. Olsen's claims (including his claim to "expedited access") are not decisions of neutral decision makers, and Mr. Olsen's due process rights under the Constitution have been violated.

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VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order:

(1) setting aside CMS-1682-R (and those portions of LCD L33822 and LCA A52464 that depend on it) and its determination that CGMs that do not completely replace finger prick/test strips are not DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(2) enjoining the Secretary from enforcing CMS 1682-R (and those portions of LCD L33822 and LCA A52464 that depend on it) ad from otherwise denying CGM claims on the grounds that a CGM is not "durable medical equipment";

(3) finding that CGMs (whether they completely replace finger prick/test strips or not) are DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(4) finding the Secretary's denials of CGM coverage on the grounds that a CGM is not DME is not supported by substantial evidence, are arbitrary and capricious, an abuse of discretion, and not in accordance with the law;

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(5) pursuant to 42 U.S.C. § 405(g) (fourth sentence) remanding this matter to the Secretary with instruction to provide coverage for claims at issue in this case; and

(6) appointing a special master to monitor the Secretary's compliance with the Court's Order and review (prior to delivery to beneficiaries) any rejection of CGM claims on the grounds that a CGM is not "durable medical equipment), such a special master having the authority to reverse a denial by the Secretary on these grounds, the special master to serve for a period of two years;

B. Award attorney's fees and costs to Plaintiffs as permitted by law; and

C. Such further and other relief (including nominal damages) this Court deems appropriate.

DATED: November 18, 2021

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